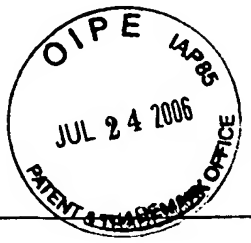


Attorney Docket: 128.004

**CERTIFICATE OF MAILING**

**I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Irving M Fishman — Type or Print Name

Signature

7/21, 2006 — Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirmation No. 9170

| | | |
|---|---|---|
| Applicant | : | Frieze, et al |
| Appl. No. | : | 10/070,621 |
| Filed | : | Mar. 5, 2002 |
| FOR | : | FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION |

Art Unit: 1744
Examiner: Krisanne Jastrzab

Docket No. : 128.004
Customer No. :

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MARCIA FRIEZE

Sir:

I, Marcia Frieze, residing at 45 Berkery Place, Alpine, NJ 07620, hereby declare and say as follows:

1. I graduated from Brooklyn College in 1967, having received a Bachelor of Arts degree in Sociology and Anthropology.

2. In 1970, I graduated from Columbia University, receiving a Master of Science degree in Social Work.

3. For one year, 1979-1980, I was employed at Piedmont Technical College in the position of Instructor.

4. From then until 1970-1982, I was employed at Montefiore, Columbia Presbyterian Psychiatric Institute, Kaiser Permanente (CA), and Family Support Center in Salt Lake City UT as a clinical social worker.

5. From then until 1994, I was employed as a Vice President at Dimedics Inc managing a mobile CT scanning service.

6. Since 1992, I have been Vice President and then CEO of Case Medical Inc., Ridgefield NJ, the owner of the above-identified application.

7. I am an author in at least 12 articles set forth below.
"Sterilization Containers" – Infection Control Today – 11/00;
"Container System Effectiveness" – SSM – 2/01;
"To Flash or Not to Flash" – Managing Infection Control – 5/01;
"Sterilization Solutions for the New Millennium" – Managing Infection Control – 6/01;
"A Case for Inventory Control" – Infection Control Today - 7/01;
"Instruments Missing in Action" – Infection Control Today – 12/01;
"Bio-terrorism: The Invisible Enemy" – SSM – 2/02;
"Making A Case For Properly Processing & Storing Endoscopes" – EndoNurse – 3/02:
"Challenges Impacting the Reprocessing of Reusable Medical Devices" – Managing Infection Control – 9/03;

"Assuming Responsibility with Sustainable Solutions" – Managing Infection Control – 1/2003;
"Flash Sterilization: A Case Study" – Managing Infection Control – 11/03;
"Loaner Instrumentation" – Managing Infection Control – 3/2005
"Cleaning the Critical First Step in the Decontamination Process" – Managing Infection Control – 6/2005;

9. I am an inventor in the above-identified application and an inventor in several other patents dealing with sterilization equipment.

10. I am familiar with the present application and the last office action in the above-identified case and give this declaration in support of Applicants arguments in favor of patentability.

11. In the Interview of November 15, 2005, the Examiner had requested that the Applicant provide a Declaration with respect to the critical nature of the anodic layer thickness limitation in the claims. That limitation is a maximum of 0.5 mils and a minimum of 0.2 mils. A declaration was submitted by me in November 2005 on this issue, but the Examiner discounted it as being an opinion declaration and not the presentation of objective data.

12. The present Declaration is provided to submit objective test data regarding the performance of aluminum sterilization containers in a gas plasma sterilization environment where those containers have anodization layers either within the current claim limits (less than 0.5 mils thick) vs greater than 0.5 mils thick.

13. Case Medical Inc.'s SteriTite containers were tested in a STERRAD® 100S Sterilizer conducted in 2000 in support of a showing of efficacy of the SteriTite containers. All such containers had anodization layer thicknesses of less than 0.5 mils. Specifically, the thickness was from 0.25 mils to a maximum 0.5 mils. The containers were tested according to Procedure 1

below. The results were that in each test of these containers, there was no post sterilization procedure growth at all.

14. In Spring of 2006, Case Medical Inc had two of its SteriTite containers (of the same sizes as were tested in 2000 as described in paragraph 13 above) modified to have anodization layer thicknesses of 1 mil instead of not greater than 0.5 mil. These SteriTite containers along with two competitor containers (Genesis, having anodization layer thicknesses of 2 mil to 3 mil) were also tested for effectiveness in May and June 2006 as set forth in Procedure 2 below. The results show that the Genesis product had substantial biological contamination after processing in the STERRAD 100S sterilizer. The results further show that the SteriTite containers with a 1 mil thick anodization layer had reductions in biological contamination, but none of the containers were completely free of biological contamination.

15. Thus, the distinction between an anodization layer of "substantially not greater than 0.5 mil (within the claims of the present application) and 1 mil (outside of the present application limits) is a critical one.

16. In an effort for complete disclosure, it should be known that the test in 2000 was conducted at ASP (Advanced Sterilization Products, a division of Johnson and Johnson), while the 2006 test was conducted at SMP GmbH in Germany. However, as can be seen below, the protocols used were either identical or the 2006 testing permitted a longer contact time between sterilization media and the substrates being sterilized, so that if there were no difference between the products, results at least as good (if not better) would have been expected from the 2006 test than from the 2000 test. In contrast to such expectation, none of the 2006 test subjects achieved sterility, while all of the 2000 test subject did. Thus, the test results show unequivocally that the results of adhering to the claim limitations are unexpected in light of the prior art.

17. The test procedures used in 2000 are as follows:
Stainless steel lumens (3 x 400 mm for full size containers and 3 x 278 mm for half size containers), stainless steel rods, stainless steel surgical blades, and glass substrates are used as test substrates. The substrates are inoculated with a minimum of $1.0 \times 10^6$ spores of Bacillus stearothermophilous ATCC 7953 and placed in the containers. The loaded containers are placed in the sterilization chamber of a STERRAD 100S sterilizer and run through a half cycle. The half cycle has an air plasma time of 10 minutes and an exposure phase consisting of 6 minutes injection, 2 minutes diffusion, and 2 minutes plasma. Upon completion of the half cycle, the test substrates are aseptically transferred into triptycase soy broth and incubated at 55-60°C. At the end of the test day, positive and negative control tubes were prepared and incubated with the test subject materials. Incubation was for 14 days and samples were read intermittently throughout the incubation period. After 14 days incubation, none of the test substrate material had any microbial growth. None of the negative controls had any microbial growth and all of the positive controls had microbial growth.

18. The test procedures used in 2006 are as follows;
Stainless steel lumens (3 x 400 mm) are used as substrates. The substrates are inoculated with 10 µl of a suspension of Geobacillus stearothermophilus ATCC 7953 (this is the same organism used 2000, formerly known as Bacillus stearothermophilous ATCC 7953) having a concentration of $1.2 \times 10^8$ cfu/ml (colony forming units per ml) so that after each is allowed to dry for 1 hour, each substrate has $1.2 \times 10^6$ cfu thereon. Half cycle sterilization in a STERRAD 100 S Sterilizer is conducted with the inoculated lumens in the test containers (1 mil anodization layer modified Case medical SteriTite containers and 2 mil to 3 mil thick anodization layer Genesis containers). The half cycle used in these tests had the following parameters. There was a 20 min 56 sec vacuum phase including preplasma, and injection phase of 6 minutes 4 sec, a diffusion phase of 2 minutes, and a plasma phase of 7 minutes, 44 sec. At the

completion of the sterilization cycle, the inoculated substrates are put into tryptic soy broth, subjected to serial dilution and plated onto tryptic soy agar, which are incubated for 24 hours at 56±1°C before colony counts are determined. The results show that for the Genesis containers the substrates much greater than 300 cfu/substrate in all cases. It also showed that the substrates sterilized in the modified (1 mil anodization layer thick) SteriTite containers, the substrates had between 10 and 270 cfu/substrate. Thus, no Genesis or modified SteriTite container allowed for complete sterilization, despite the fact that the unmodified SteriTite containers permitted complete sterilization in the 2000 testing.

19. These results are even more dramatic when one compares the differences in the two short half test procedures:

| Parameter | 2000 Protocol | 2006 Protocol |
|---|---|---|
| Half Cycle: | | |
| Air plasma time | 10 min | 20 min 56 sec |
| Exposure phase | | |
| Injection | 6 minutes | 6 min 4 sec |
| Diffusion | 2 minutes | 2 min |
| Sterilant Plasma | 2 minutes | 7 min 44 sec |
| Incubation before reading | | |
| | tryptic soy both tubes | tryptic soy agar |
| | 14 days | 1 day |

Note especially that the 2006 procedure had an exposure to plasma which was more than 3 times that in the 2000 tests so that one would expect greater sterilization from the 2006 procedure. Also note that incubation in a liquid media would be expected to be better than in a solid media, so again, the 2006 test would have been expected to have lesser growth than the 2000 test (all other factors being equal). Finally, note that the incubation time in the 2000

test was 14 days, while the 2006 incubated for only 1 day. Thus, again the 2006 test procedure would have been expected to have lesser growth than in the 2000 test. Had the incubation period in the 2006 test been for 14 days, much larger amounts of growth would have been evident. Thus, all of the differences between the two test procedures (which are not many at all) all point to the results being even more dramatic than would first appear.

20. Further, in addition to inoculated substrates in the containers, the 2006 study included inoculated substrates in permeable peel pouches placed in the sterilizer at the same time as test containers, but not in the containers. These were processed through the STERRAD 100S Sterilizer and post sterilizer processing were in the same manner as the substrates that were processed in containers. The STERRAD 100S Sterilizer has a built in fail safe and warning which is designed to abort the process if sterilization is not taking place. However, when containers having 1 or 2-3 mil thick anodization layers were present within the sterilizer, even the substrates in the permeable peel pouches did not sterilize, but the fail safe abort mechanism and warning did not trigger. This meant that not only did biological kill not take place in the containers, but that other items in the chamber could be affected by absorption of the sterilant into the thicker anodized coating which restricted sterilant penetration into the containers within the sterilizer and within a peel pack.

21. Based on the foregoing, it is believed that the unexpected nature of the "substantially not greater than 0.5 mil" limitation on anodization layer thickness of the claims has been established.

22. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false

statements may jeopardize the validity of this patent application and any patent issuing thereon.

Respectfully submitted,

Marcia Frieze

Marcia Frieze

Date: July 21, 2006